**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**TEXARKANA DIVISION**

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| Health Choice Group, LLC and Jaime Green, on behalf of the United States of America, et al.,<br><br>Plaintiffs/Relators,<br><br>v.<br><br>Bayer Corporation; Amgen Inc.; Onyx Pharmaceuticals, Inc.; AmerisourceBergen Corporation; and Lash Group,<br><br>Defendants. | Civil Action No. 5:17-cv-126-RWS-CMC |

**DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS FIRST AMENDED COMPLAINT**

Relators' opposition brief reflects a hope that the length of their First Amended Complaint ("FAC") can mask its legal errors and lack of specificity. Among other things, Relators ask the Court to ignore regulatory guidance and safe-harbor provisions that squarely address the acts alleged and make recovery impossible. The "schemes" alleged are common practices in the industry and fall within the scope of these regulatory materials from the U.S. Department of Health and Human Services. Relators do not allege that Defendants undertook any unusual variation of these practices. Their claims are merely blanket attacks on established practices that previously have been addressed and accepted.

Even ignoring those hurdles, Relators fail to provide the "particular" specifics required to survive this motion to dismiss—a requirement that the Fifth Circuit instructs must be applied with "bite" and "without apology."[1] It is not enough to allege expansive schemes and avoid the need for specifics as to what was done and by whom, and how it caused a false claim to be submitted to the Government for reimbursement. Relators' claims should be dismissed.

## I. Relators Have Not Alleged Facts To Show A Plausible FCA Claim.

### A. There is no "false" claim because there was no AKS violation.

Relators do not dispute that they must show Defendants committed an AKS violation to satisfy the "falsity" element of their pled FCA claims. But their opposition brief demonstrates both a misunderstanding of AKS law and a lack of facts to show a plausible violation occurred.

#### 1. Relators have failed to show an AKS violation through either the reimbursement or nurse support services (Theories One and Three).

Long-standing OIG Guidance states that support services provided by a pharmaceutical manufacturer do not implicate the AKS if they are "tied to support of the purchased product" and offer no substantial independent value. HHS OIG Compliance Program Guidance for

[1] *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 178 (5th Cir. 1997).

Pharmaceutical Manufacturers ("OIG Guidance"), 68 Fed. Reg. 23731 § II.B(2)(b)(B)(1)(a), 2003 WL 2010428, at *23735. Defendants' alleged acts fall well within this guidance, so Relators spend the majority of their opposition brief arguing that it does not apply here. They incorrectly claim this provision of the OIG Guidance applies only if the services assist "purchasers." Doc. 52, Opp. to Mot. to Dismiss ("Opp.") 7-8. Where, as here, the services allegedly helped "physicians," they assert a different and lower standard applies, whereby a kickback occurs from any service that "would 'eliminate an expense the physician would have otherwise incurred[.]'" *Id*. at 7. This purported "test" for an AKS violation—a criminal statute—is made up from whole cloth and is wrong for several reasons.

The argument is refuted by the plain text of the OIG Guidance itself, which does not declare blanket AKS liability for any service that might "eliminate an expense" for a physician. At most, it cautions that if services "eliminate an expense that the physician would have otherwise incurred (i.e., *have independent value to the physician*), . . . the arrangement *may be problematic*." OIG Guidance, 2003 WL 2010428, at *23737 (emphasis added). Manufacturers are then directed to either structure the arrangement to "fit in an available safe harbor" or to consider "the totality of all facts and circumstances" to ensure AKS compliance. *Id*. This careful guidance is a far cry from Relators' position that all product-support services automatically create criminal liability. To the contrary, it comports with the OIG Guidance's explicit approval of product-support services with no independent value.

Because free product-specific services are common in the industry, the OIG itself performed that "facts and circumstances" analysis and directed pharmaceutical manufacturers in the OIG Guidance that such services do not violate the AKS when they are tied to a particular product and provide no substantial independent value. *Id*. at *23735. This specific and express

OIG Guidance controls here, not the OIG's more general caution to the industry to do a "fact and circumstances" analysis when providing other services. Moreover, the OIG's specific advice for product-specific services is entirely consistent with its broader cautionary language upon which Realtors' rely—both find no AKS implications as long as the services do not confer an "independent value" to the receiving physician or purchaser. *Id*. at *23735, *23737.

Relators' purchaser-physician distinction is similarly meritless. The OIG Guidance was issued fifteen years ago, but Relators could not present a single authority in their brief that limited that document in the way that Relators now ask. Instead, their cited caselaw (and Defendants') shows that courts consistently apply the same OIG Guidance to services provided to physicians. *See, e.g., U.S. ex rel. Wood v. Allergan, Inc*., 246 F. Supp. 3d 772, 807 (S.D.N.Y. 2017), *motion to certify appeal granted*, No. 10-CV-5645 (JMF), 2017 WL 1843288 (S.D.N.Y. May 4, 2017) (analyzing OIG Guidance's language in context of benefits given to physicians and noting defendant's argument "is not without some force given the language of the . . . Office of Inspector General's Guidelines"); *U.S. ex rel. Forney v. Medtronic, Inc*., No. CV 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) (looking to OIG Guidance and dismissing claims of AKS violations allegedly caused by product-specific services provided to physicians). The OIG Guidance discusses both physicians and purchasers throughout, *expressly referencing providers* with respect to "Product Support Services." OIG Guidance, 2003 WL 2010428, at *23735 (""[I]f a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program *that confers a benefit on a referring provider* (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns.") (emphasis added)).

Finally, Relators' artificial distinctions ignore the OIG's other statements on this issue, which were expressly directed to services to physicians and took the same approach contained in the 2003 OIG Guidance. The OIG issued an advisory opinion in 2000—three years before the OIG Guidance was issued—finding that assistance given by "[d]rug manufacturers . . . *to physicians*" regarding insurance coverage and reimbursement levels "do not implicate the [AKS]" because the services "have no independent value to providers apart from the products[.]" OIG Adv. Op. 00-10, 2000 WL 35747420, at *4 (emphasis added). Relators argue that the OIG's findings must be limited to the particular facts of the opinion, but even if that were so, the facts are strikingly similar to those alleged here. Moreover, courts routinely consider Advisory Opinions as persuasive authority.[2]

When viewed under the proper standard, the FAC does not state a plausible AKS violation. None of Relators' allegations show either service provided physicians with a value independent of the medicines. In a single paragraph, Relators contend—without citation to facts alleged in the FAC—that the reimbursement services used for the medicines *could* be used by physicians later for "all of their patients." Opp. 12. This does not demonstrate a substantial independent value actually given to the physicians, and it therefore cannot save Relators' claims.

With respect to nurse education services, Relators claim independent value existed because nurses educated cancer and multiple sclerosis patients "how to manage their treatment and underlying disease." *Id*. This assertion, however, confirms the services were provided only to patients that received the medicines (i.e. they were "tied to the product"). *See Medtronic*,

[2] *See, e.g.*, *U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-CV-3396, 2015 WL 5178074, at *20 n.9 (S.D. Tex. Sept. 3, 2015), *aff'd sub nom. U.S. ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368 (5th Cir. 2016) (citing to OIG Advisory Opinion No. 08-03 for the proposition that "prompt-pay discounts are legitimate if the discount is a 'pragmatic financial decision' and not intended to induce referrals"); *First Am. Bank v. Resolution Tr. Corp.*, 30 F.3d 644, 649 (5th Cir. 1994) (discussing FDIC Advisory Opinion 89–11 and FDIC Advisory Opinion 90–03 and noting "that FDIC Advisory Opinion 89–11 is consistent with [the court's] interpretation of the statute.").

2017 WL 2653568, at *4 ("Offering well-supported products might induce physicians to purchase Medtronic products, but only because they are better-supported products than competing products.").[3]

2. Relators have failed to show an AKS violation through the nurse educator program (Theory Two).

The FAC incorrectly claims that "the AKS prohibits pharmaceutical companies from paying non-employees to 'recommend' its drugs to others." FAC ¶ 114. Defendants' opening brief explained that is not the law, Doc. 38, Mot. to Dismiss ("MTD") 14, and Relators do not dispute this in their brief. That concession alone warrants dismissal.

Despite having conceded that it is not illegal to hire third parties to promote a drug, Relators' brief simply repeats legally irrelevant allegations that the nurse educators acted as "sales reps." Opp. 12-13. Simply labeling the nurses as "sales reps" does not reach the line for AKS liability. *See United States v. Shoemaker*, 746 F.3d 614, 627 (5th Cir. 2017) (noting elements for AKS claim include remuneration "knowingly and willfully" paid "to induce the recipient . . . [to] recommend procuring a covered healthcare good or service"). Moreover, the actual allegations concerning the conduct of the confidential interviewees are consistent with product education, not "recommendations." MTD 6-7. For example, none of the nurse educator "Confidential Interviewees" quoted by Relators in the FAC allege to have undergone any sales or

[3] Relators' cases are distinguishable and only highlight that no illegal conduct is alleged here. In *U.S. ex rel. Wood v. Allergan, Inc*., defendants were not alleged to have provided any services to support the patients' use of the prescribed drug, but instead were alleged to have given physicians free products that they would otherwise have purchased themselves: millions of free drug samples, physician-branded patient instruction sheets, and physician-customized prescription pads. 246 F. Supp. 3d at 806-09. Unsurprisingly, then, defendants in *Wood* did not even argue that those benefits were product support services and permissible under the OIG Guidance. *Id*. In *U.S. ex rel. Boise v. Cephalon, Inc*., the complaint did not allege, and the court did not find, that merely providing product-specific free reimbursement services would violate the AKS. No. 08-287, 2015 WL 1724572, at *11 (E.D. Pa. Apr. 15, 2015). Instead, the allegations were that those services were the last link in a larger scheme to induce physicians to improperly prescribe products for off-label uses (uses not approved by the FDA) primarily through the inducements of improper speakers' fees. *Id*. As the court stated, the allegations of "free reimbursement services merely provide one more detail in what is a properly alleged over-arching scheme of kickback violations and off-label promotion." *Id*.

marketing training.[4] Yet Relators make unreasonable and unsupported inferences from the interviewee's actual statements. This is not enough to state a claim. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("Factual allegations must be enough to raise a right to relief above the speculative level."); *Griffin Indus. v. Irvin*, 496 F.3d 1189, 1205-06 (11th Cir.2007) ("Our duty to accept the facts in the complaint as true does not require us to ignore specific factual details of the pleading in favor of general or conclusory allegations.").

Relators' last argument to escape the applicable safe harbor provisions is entirely circular. The safe harbor expressly states that practices that fall within its provisions "shall not be treated as a criminal offense under" the AKS. 42 C.F.R. § 1001.952. But Relators argue that provision cannot apply to Defendants' actions because those actions violated the AKS. Opp. 14. Under this reasoning, the safe harbor provision would never apply, contrary to the OIG's intent in protecting certain conduct.

**B. Relators have failed to show Defendants knowingly presented a false claim.**

Relators do not dispute that Defendants are not liable if their alleged conduct is based on reasonable interpretations of the law. Opp. 16. As previously shown, the OIG Guidance—and the absence of other clear guidance stating that Defendants' conduct would be unlawful—demonstrates the objective reasonableness of Defendants' position and precludes a finding of "knowing" violation.

Relators contend they should nonetheless prevail here because, they claim, discovery is needed to establish actual reliance on that reasonable interpretation and scienter therefore can never be resolved on a motion to dismiss. *See id.* at 16-17. That is not the law. In *U.S. ex rel. Nevyas v. Allergan, Inc.*, for instance, the court noted that because defendant's argument

[4] While Relator Jamie Green alleges that she received sales training with regards to the product Adempas, there are no allegations that any of the Confidential Interviewees received sales training for either Betaseron or Nexavar.

"focuse[d] on its state of mind," the issue *in that case* required development of the factual record. No. 09-432, 2015 WL 4064629, at *6 (E.D. Pa. July 2, 2015). The court did not rule that scienter is never appropriate for a motion to dismiss. To the contrary, it acknowledged—and did not disagree with[5]—*U.S. ex rel. Streck v. Allergan, Inc.*, which dismissed allegations for failure to plead scienter after the court assessed the "regulatory framework" and found that "there was nothing that 'warned' [defendants] away from the view [they] took' on an interpretation of regulations . . . ." *Id*. at *5-6 (quoting *Streck*, 894 F. Supp. 2d 584, 596, 600 n.11 (E.D. Pa. 2012)).[6]

Here, unlike in *Nevyas*, Defendants do not ask the Court to inquire into their state of mind or determine factual issues; they have instead shown that the regulatory framework and guidance—whose interpretation is for the Court—preclude a finding of a "knowing" violation.[7]

Relators also cite to *U.S. ex rel. Wood v. Allergan, Inc.*, but the court there *did* analyze whether the defendant's interpretation was objectively reasonable on a motion to dismiss. 246 F. Supp. 3d at 829. It ultimately denied the motion, but only after finding the "detailed allegations" in the complaint created questions of fact that defendant's "position may not have been objectively reasonable at the time of the alleged violations," namely the allegations that: 1) defendant's "own internal documents 'strictly prohibited'" some of the alleged conduct; 2) the OIG Guidance warned defendant not to engage in the conduct; and 3) defendant admittedly was "aware and concerned about its potential liability under the AKS, prompting the company to

[5] The *Nevyas* court found the *Streck* opinion did not create a "substantial ground for a difference of opinion" in the Third Circuit for purposes of certifying the question for interlocutory appeal. *Nevyas*, 2015 WL 4064629, at *5-6.
[6] The court in *Streck* also found that plaintiffs failed to plead that defendants' "interpretation of the statutory and regulatory scheme was unreasonable, let alone that [defendants'] interpretation raised 'the unjustifiably high risk of violating the statute necessary for reckless liability.'" *Streck*, 894 F. Supp. 2d at 595-96 (quoting *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 (2007)).
[7] Moreover, (and as Relators acknowledge), the court in *Nevyas* explained that defendant's "reasonable interpretation of the law" argument was inappropriate on its motion to dismiss "when there are reasonable interpretations to the contrary." 2015 WL 4064629, at *6. Here, in contrast, the only contrary interpretation of the Guidance that Relators have offered is unsupported and unreasonable.

stop." *Id*. No such allegations are presented here.[8] The Court can and should decide the scienter issue on this motion to dismiss. *See United States v. Sodexho, Inc.*, No. 03-6003, 2009 WL 579380, at *17 (E.D. Pa. Mar. 6, 2009), *aff'd sub nom. U.S. ex rel. Pritzker v. Sodexho, Inc.*, 364 F. App'x 787 (3d Cir. 2010) (assessing "reasonableness of . . . position" on motion to dismiss and finding "lack of clarity regarding the proper interpretation of the regulations indicates that no basis exists for imposing FCA liability on Defendants, who merely adopted a reasonable interpretation of regulatory requirements which favored their interests.").

Relators' final argument is even if this issue can be resolved now, they have alleged sufficient facts. Relators agree they must allege facts to "support an inference that Defendants acted with the intent to violate the AKS . . . [and] knew . . . these kickbacks would result in the submission of false claims." Opp. 19. But the "facts" they point to are only legal conclusions. *See, e.g., id*. ("Defendants disregarded the law."), *id*. at 21 ("[T]he goal of Defendants' conspiracy was to try to 'disguise their marketing strategy' and 'circumvent the law.'").[9] Relators have not sufficiently alleged the requisite scienter.

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[8] Relators' remaining citations on this issue are equally unavailing. *See U.S. ex rel. Banigan v. Organon USA, Inc.*, No. CIV.A. H-08-3314, 2013 WL 4786323, at *2 (S.D. Tex. Sept. 6, 2013) (discussing issue of objective reasonableness only in context of certifying for appeal the question of whether that standard should apply); *United States v. Newman*, No. CV 16-1169 (CKK), 2017 WL 3575848, at *8 (D.D.C. Aug. 17, 2017) (declining to dismiss case where allegations were "merely . . . rebutted by assertions about Defendant's state of mind"—an issue not present here, as Defendants are not merely "rebutting" Relators' allegations but are demonstrating why they are insufficient standing alone); *U.S. ex rel. Pasqua v. Kan-Di-Ki LLC*, No. CV 10-965-JST (RZX), 2012 WL 12895229, at *7 (C.D. Cal. June 18, 2012) (noting that "while ambiguity is relevant to the scienter inquiry, it does not preclude a finding of liability under the FCA unless no issues of fact remain"—which is irrelevant because Defendants here do not claim that any ambiguity in the OIG Guidance precludes a finding of liability); *United States v. Estate of Rogers*, No. 1:97CV461, 2001 WL 818160, at *4 (E.D. Tenn. June 28, 2001) (addressing arguments as to the *falsity* element, and mentioning only in passing "the *separate issue* of scienter") (emphasis added).

[9] A review of the cases upon which Relators rely shows those contained far more detailed allegations than those presented here. *See United States v. Americus Mortg. Corp.*, No. 4:12-CV-02676, 2014 WL 4274279, at *10 (S.D. Tex. Aug. 29, 2014) ("Government provide[d] details of Allied Corp's fraudulent scheme, including instances where employees were directed to disregard quality-control measures and to 'make it appear' as if Allied Corp had complied with HUD's requirements."); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 670 (S.D. Tex. 2013), *aff'd sub nom. U.S. ex rel. Parikh v. Brown*, 762 F.3d 461 (5th Cir. 2014), *opinion withdrawn and superseded on reh'g*, 587 F. App'x 123 (5th Cir. 2014), *withdrawn from bound volume* (Oct. 1, 2014), *and aff'd sub nom. U.S. ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014) (among "several" allegations providing strong inference of kickback scheme, court noted "allegations that the cardiologists' income more than doubled after they

## II. The FAC Fails To Satisfy The Fifth Circuit's Rule 9(b) Standard, Which Relators Misconstrue And Dilute.

The FAC fails Rule 9(b)'s standard because it does not provide adequate details of the alleged scheme and because it does not contain "*reliable indicia* that lead to a *strong inference* that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (emphasis added).

### A. Relators' "detailed allegations" describe established programs without any details required by Rule 9(b) as to how the programs violate the AKS.

Relators incorrectly argue in their opposition that they can satisfy Rule 9(b) without pleading key details regarding the alleged activities and how those activities run afoul of the AKS and the FCA. Opp. 24. But just last year, in an FCA case, the Fifth Circuit reiterated that to avoid dismissal under Rule 9(b), a relator must, at minimum, set forth the "who, what, when, where, and how" of the alleged fraudulent scheme. *U.S. ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 371 (5th Cir. 2017). Consistent with this, multiple courts in this Circuit have dismissed FCA cases for precisely the lack of detail exhibited by the FAC. *See, e.g., U.S. ex rel. Stephenson v. Archer W. Contractors, L.L.C.*, 548 F. App'x 135, 139 (5th Cir. 2013).[10]

Notably, Relators misquote and mischaracterize *U.S. ex rel. Wall v. Vista Hospice Care, Inc*., 778 F. Supp. 2d 709, 720 (N.D. Tex. 2011), for the proposition that "'Relators do not have to identify the specific individuals who participated in the fraud,' nor do they have to provide specific dates or locations of instances of the fraud within the alleged scheme." Opp. 26. The excerpt upon which Relators rely, however, was only a restatement of the defendant's argument; it was not the court's holding. *See Wall*, 778 F. Supp. at 720. Although a few of the relators'

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joined Citizens, even while their own practices were costing Citizens between $400,000 and $1,000,000 per year in net losses.").

[10] For other examples of courts in the Fifth Circuit dismissing FCA cases for lacking sufficient detail about the fraud, *see* Defendants' Motion to Dismiss at 21-25 & n.6.

claims survived, the court dismissed claims for failing "to satisfy the 'who,' 'where,' and 'what" requirements of Rule 9(b)" *despite* noting that relator had "specifically . . . identified [patients] by their initials," provided "specific dates ('when')", and that "for a number of allegedly improper certifications [to the government], [relator] provide[d] patient initials, dates, and medical information about patients." *Id*. at 716, 719.

While Relators assert that they set out allegations in "dozens of detailed paragraphs," Opp. 22, they fail to address the fact that the FAC omits these essential details. The allegations amount to descriptions of established industry practices long-known to regulators, addressed specifically in the OIG Guidance, and covered by the safe harbor provisions of the AKS. *Supra*, Part I.A.1-2. Perhaps Relators' most glaring defect under Rule 9 is their failure to provide any detail whatsoever regarding how the alleged product-support activities go beyond OIG Guidance and AKS safe harbors to provide illegal remuneration to prescribers. That is the linchpin of their case, without which there can be no AKS violation and, in turn, no FCA violation.

As Defendants pointed out in their opening brief, Relators have pled no facts suggesting that some improper variation of those support services models occurred, or that Defendants took some additional step to provide independent value to prescribers. MTD 23. Unsurprisingly, Relators' opposition brief provides essentially no rebuttal. *See* Opp. 27.[11] Instead, they generally allege and argue that that nurse educators are paid a salary; that Defendants provided patient follow up (tailored to the drugs already prescribed); and that vague "tangible benefit" associated with well-supported products violates the AKS. *Id*. Relators cannot satisfy Rule 9 with such general descriptions of uncontroversial industry practices. *See Medtronic*, 2017 WL 2653568, at *4-5. And Relators cannot dismiss as a "red herring" the requirement that they

[11] Relators do not contend, for example, any of their interviewees were instructed to provide services to HCPs beyond mere support of the medicines prescribed by their physicians.

plead some plausible means by which the product support services at issue actually and substantially provide independent value to prescribers in a way that implicates the AKS.[12]

**B. Relators have not met the "reliable indicia" standard for showing that Defendants' activities caused the submission of false claims.**

The FAC also fails under Rule 9(b) because it does not tie any of the alleged support activities to the submission of a false claim to the government. Although Relators claim they "do not need to identify any actual referrals or successful inducements to prove a violation of the AKS," Opp. 26, conclusory allegations that false claims were submitted are "insufficient to serve as 'reliable indicia that leads to a strong inference that false claims were actually submitted.'" *U.S. ex rel. Vavra v. Kellogg Brown & Root, Inc.*, 903 F. Supp. 2d 473, 487 (E.D. Tex. 2011), *rev'd on other grounds*, 727 F.3d 343 (5th Cir. 2013) (quoting *Grubbs*, 565 F.3d at 189). Relators point to disparate pieces of information attempting unsuccessfully to argue that such an inference can be drawn. They also relegate the multitude of cases cited by Defendants where courts dismissed complaints for similar failings to a footnote, Opp. n.8, conceding that the complaints in those cases were insufficient but not explaining how the FAC should fare any better in light of similar deficiencies.

Pasting summaries of aggregate annual reimbursement amounts by Medicare and Medicaid for one or more of the products at issue into the FAC does not absolve Relators from their obligations under Rule 9(b). *See* MTD 29-30. As Defendants explained in their opening brief, the charts at FAC ¶¶ 192-204 show the collective government reimbursement figures to all

[12] Relators cite *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997), for the proposition that "[t]he pleading requirements of Rule 9(b) are [] relaxed where . . . facts relating to the alleged fraud are peculiarly within the defendant's knowledge." Opp. n.6. Relators omit the rest of the cited paragraph, where the court warned that "this exception must not be mistaken for license to base claims of fraud on speculation and conclusory allegations," and actually dismissed the claims at issue as inadequately plead. *Id.* at 903 (quotations omitted). Moreover, the allegations in this action are not "peculiarly within the defendants' knowledge." *Id.* For instance, Relators purport to have conducted hundreds of interviews with former employees regarding the support activities at issue. Opp. 3.

(unidentified) doctors practicing in the state, without any indication that those statewide payments had anything to do with any alleged kickback from Defendants.[13]

Moreover, the cases Relators cite in an effort to minimize their burden to connect alleged fraud to the submission of claims are unpersuasive. For instance, they cite an earlier district court opinion in *U.S. ex rel. King v. Solvay*, Opp. 31, without acknowledging a subsequent Fifth Circuit decision from the same case concluding that "it would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe [defendant's] drugs to Medicaid patients." *See U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.*, 871 F.3d 318, 332 (5th Cir. 2017). The remaining cases Relators cite where courts found that relators had sufficiently alleged a causal link between fraudulent conduct and the submission of false claims involve allegations or facts far more detailed than those in the FAC.[14]

Finally, Relators' allegation that the alleged fraud resulted in increased prescriptions is conclusory and insufficient. Relators provide summary figures for reimbursements for a handful

[13] To the extent Relators argue that the fifteen anonymous doctors cited in FAC ¶ 189 close this gap, Defendants refer the Court to their Motion to Dismiss. *See* MTD 22-25, 28-29 (explaining that Relators have not alleged that Defendants provided any services whatsoever to nine of the fifteen doctors listed in Paragraph 189, and that even as to the six remaining doctors, they have not made the necessary connection that the doctors submitted any claims through Government healthcare programs).

[14] *See U.S. ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1039-41 (C.D. Cal. 2016) (relator demonstrated causation with empirical evidence that "physicians who received more promotional contacts" prescribed at higher rates); *U.S. ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.*, No. 3:14-CV-00118-M, 2016 WL 5661644, at *2-10 (N.D. Tex. Sept. 30, 2016) (complaint identified specific individuals connected to the fraud, referred to discrete instance of false coding, and detailed the numeric value obtained by defendant in connection with each instance of fraudulent conduct); *U.S. ex rel. Cestra v. Cephalon, Inc.*, No. CIV.A. 14-1842, 2015 WL 3498761, at *5 (E.D. Pa. June 3, 2015) (alleged fraudulent conduct was specifically aimed at getting reimbursements "from government programs" and relator provided specific profit figures generated by such conduct); *U.S. ex rel. Tucker v. Christus Health*, No. CIV.A. 09-1819, 2012 WL 5351212, at *4 (S.D. Tex. Oct. 23, 2012) (the complaint "identifie[d] by name individuals who participated in submitting the false claims to Medicare . . . specifie[d] the time period during which the false claims were submitted to Medicare . . . provide[d] specific examples of each category of fraudulent billing, and explain[ed] that Defendants received millions of dollars thereby."); *United States v. Toyobo Co.*, 811 F. Supp. 2d 37, 48 (D.D.C. 2011) (causation was self-evident based on allegations that Defendant sold manufacturers a material it knew to be defective to make bullet-proof vests, which the manufacturers then sold to the government); *U.S. ex rel. DeKort v. Integrated Coast Guard Sys.*, 705 F. Supp. 2d 519, 539, 545 (N.D. Tex. 2010) (relators provided "copious detail" including several of the actual alleged false claims, such as Certificates of Compliance).

of years, all of which fall within the time period in which the alleged fraud was already ongoing. *See* FAC ¶¶ 192-204. They point to no comparison figures which might serve to support their flimsy allegations that the programs resulted in increased prescriptions. *See* Opp. 29-30. Moreover, Defendants' services need not be wrongful for them to result in increased prescriptions; as the *Medtronic* court observed, "[o]ffering well-supported products might induce physicians to purchase [Defendants'] products, but only because they are better-supported products than competing products." *Medtronic*, 2017 WL 2653568, at *4.

## III. Relators Fail To Plead Sufficient Facts To Suggest Discovery Will Reveal Evidence Of An Alleged Conspiracy.

Contrary to Relators' contention that their allegations contain "sufficient evidence to allow a reasonable inference that Defendant[s] implicitly agreed to a scheme that would result in . . . false claims," Opp. 34, they fail to identify specific allegations that satisfy the necessary conspiracy elements. First, Relators argue that "all defendants were aware of the AKS and disregarded the fact that the alleged schemes violated the AKS." *Id*. In support, Relators cite to paragraph 16 of the FAC and nothing else. *Id*. However, paragraph 16 says nothing whatsoever about Defendants' supposed awareness about any AKS violations. FAC ¶ 16. Second, Relators argue that "each of the defendants had a critical role, described in detail, in the alleged schemes." Opp. 34. However, rather than describing each defendant's "critical role" or doing so "in detail," many of the allegations that Relators reference are couched in terms of generalities using such prefaces as, "[i]n general," "[g]enerally," "[i]n sum," and "[p]ut simply." *Id*. (referencing FAC, ¶¶ 46, 96, 107, 145, and 150). Similarly, without offering specifics, Relators reference allegations that certain defendants engaged in general business activities "with [substantial] assistance from" Amerisource and Lash." *Id*. (referencing FAC, ¶¶ 88, 89, 91, 108, and 146). Third, Relators argue that they have sufficiently alleged that the purpose of the Defendants'

cooperation was to hide AKS violations, and direct the Court's attention to paragraphs 4-6 of the FAC. *Id*. at 34-35. However, those paragraphs consist of general allegations and do not set forth any "meeting of the minds" among Defendants as required by law. *See U.S. ex. rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 274 F. Supp. 2d 824, 857 (S.D. Tex. 2003). Accordingly, the Court should dismiss Relators' conspiracy claim.[15]

## IV. Relators' FAC Fails To Account For The "Meaningful Distinctions" They Now Reference For The First Time Or To Set Forth Specific Allegations In Support Of Such State-Specific Claims.

Relators make two arguments in support of their state law claims. First, they argue that there are unspecified "meaningful distinctions" between federal and state AKS and FCA violations. Opp. 36. Yet, the FAC's invocation of these state statutes makes no attempt to identify or account for such distinctions. Relators reference a single state's statute—the State of Texas's TMFPA—to support its sweeping generalization, arguing that causation is not a precondition for recovery. *Id*. To the contrary, the TMFPA (similar to the FCA) requires Relators to prove certain amounts were paid "**as a result of** the unlawful act." *Tex. Hum. Res. Code* § 36.052(a)(1) (emphasis added). Relators ignore this language and apparently construe the TMFPA as a strict liability statute.[16] Relators are incorrect and their argument fails.

Second, in their effort to rebut Defendants' argument that Relators' state claims fail because the FAC does not contain state-specific allegations, Relators actually reinforce Defendants' argument with their general allegations of "nationwide" conduct. Opp. 36. However, other than identifying the CI's "territories," the FAC (like Relators' Opposition) is

[15] As support, Relators principally rely on *Waldmann v. Fulp*, a case in which the relators alleged a series of specific facts to establish that the defendants had an *explicit* agreement. 259 F. Supp. 3d 579, 586, 631 (S.D. Tex. 2016). There are no such allegations here.

[16] The State of Texas's Statement of Interest similarly disregards this element of causation. Doc. 54.

silent as to which specific alleged misconduct took place in which specific state. *Id.* Accordingly, Relators' state claims should be dismissed.

## V. Green Was Not Properly Added To The Case And Should Be Dismissed.

Relators argue that "simply fil[ing] an amended complaint with an additional relator" does not implicate the first-to-file rule. Opp. 38. Relators are incorrect. Regardless of *how* a new relator comes to be added, the dispositive issue is whether or not that additional relator adds something new to the complaint. *See Capshaw v. White*, No. 3:12-CV-4457-N, 2017 WL 3841611, at *4-6 (N.D. Tex. Jan. 23, 2017) (even where second relators "alleged remuneration in a different form," court found they alleged "same essential facts and claims of fraud" as first relator and dismissed them from consolidated case under first-to-file rule).[17] Because she does not, Green should be dismissed.

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Respectfully submitted,

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[17] The cases on which Relators rely are distinguishable. *See United States Ex rel. Fisher v. Ocwen Loan Servicing, LLC*, Nos. 4:12-CV-543, 4:12-CV-461, 2016 WL 3031713, at *1 (E.D. Tex. May 25, 2016) (noting that the original complaint alleged violations of the Truth in Lending Act, while the first amended complaint "incorporated new allegations" concerning Federal Housing Administration violations, Dodd-Frank Act violations, etc.); *United States v. Homeward Residential, Inc*., No. 4:12–CV–461, 2015 WL 3776478, at *4 (E.D. Tex. June 17, 2015) (concluding that the addition of a relator was proper precisely because the relator had "not merely joined the previously asserted allegations, but ha[d] made new allegations within the amended complaint").

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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing document was filed electronically in compliance with Local Rule CV-5(a). Therefore, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email on this the 9th day of April, 2018.

*/s/ Andrea Fair*